



Docket No. 15672US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

C. Randal Mills *et al.*

Serial No.: 10/828,653

Filed: April 20, 2004

For: Process and Apparatus for
Treating Implants
Comprising Soft Tissue

Examiner: Not Yet Known

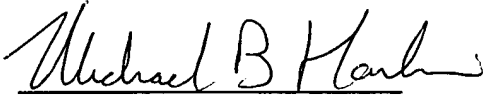
Group Art Unit: 3738

Confirmation No.: 4918

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By:


Michael B. Harlin
Reg. No. 43,658

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
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Dear Sir:

Pursuant to the Applicants' continuing duty of disclosure under 37 C.F.R. §1.56, the Applicants wish to file this Information Disclosure Statement ("IDS") under 37 CFR §1.97(c). This disclosure is also accompanied by two copies of Form PTO 1449.

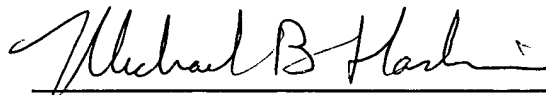
Pursuant to 37 C.F.R. §1.97(g) and (h), the disclosure of these references in this Information Disclosure Statement shall not constitute a representation that a search for

prior art was made or an admission that the references are material or that they are prior art.

Because this Information Disclosure Statement is being submitted before receipt of a first Office Action, it is believed no fees are due. However, in the event that any fees are required for the filing of this document, the Commissioner is authorized to charge our Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

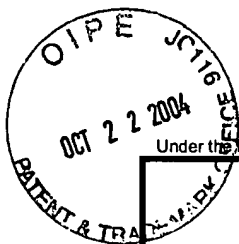
Respectfully submitted,

Date: October 20, 2004

A handwritten signature in cursive script, reading "Michael B. Harlin", written over a horizontal line.

Michael B. Harlin
Reg. No. 43,658
Attorney For Applicant

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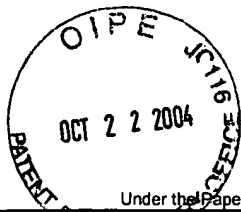
PTO/SB/21 (08-00)

Approved for use through 10/31/2002

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TRANSMITTAL FORM		Application Number		10/828,653			
(to be used for all correspondence after initial filing)		Filing Date		April 20, 2004			
		First Named Inventor		C. Randal Mills et al.			
		Group Art Unit		3738			
		Examiner Name		Not Yet Known			
Total Number of Pages in This Submission		9		Attorney Docket Number		15672US01	
ENCLOSURES (check all that apply)							
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> PTO 1449/08A with 68 references <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) (sheets) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____		<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):			
		Remarks					
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT							
Firm or Individual Name		McAndrews Held & Malloy, Ltd.					
Signature		<i>Michael B Harlin</i>					
Date		October 20, 2004					
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Name (Print/type)		Michael B. Harlin		Registration No. (Attorney/Agent)		43,658	
Signature		<i>Michael B Harlin</i>				Date	October 20, 2004



PTO/SB/08A (08-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/828,653
Filing Date	April 20, 2004
First Named Inventor	C. Randal Mills et al.
Group Art Unit	3738
Examiner Name	Not Yet Assigned
Attorney Docket Number	15672US01

U.S. PATENT DOCUMENTS

Examiner Initial*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	3,291,640	12/1966	Livingston	
	A2	4,193,818	03/1980	Young et al.	
	A3	4,294,753	10/1981	Urist	
	A4	5,037,437	08/1991	Matsen, III	
	A5	5,066,578	11/1991	Wikman-Coffelt	
	A6	5,213,619	05/1993	Jackson et al.	
	A7	5,288,462	02/1994	Carter et al.	
	A8	5,298,222	03/1994	O'Leary	
	A9	5,333,626	08/02/94	Morse et al.	
	A10	5,380,826	01/1995	Castor et al.	
	A11	5,397,357	03/14/95	Schmieding et al.	
	A12	5,429,810	07/1995	Knaepler et al.	
	A13	5,509,968	04/1996	Carr	
	A14	5,513,662	05/07/96	Morse et al.	
	A15	5,556,379	09/1999	Wolfenbarger et al.	
	A16	5,556,428	09/17/96	Shah	
	A17	5,593,844	11/1999	Abraham et al.	
	A18	5,711,921	01/1998	Langford	
	A19	5,716,454	02/1998	Carr	
	A20	5,725,579	03/1998	Fages et al.	
	A21	5,753,195	5/1998	Langford et al.	
	A22	5,769,893	06/23/98	Shah	
	A23	5,797,871	08/25/98	Wolfenbarger, Jr.	
	A24	5,846,484	12/1998	Scarborough et al.	
	A25	5,976,104	11/02/99	Wolfenbarger, Jr.	
	A26	6,001,106	12/1999	Ryan et al.	
	A27	6,024,735	02/15/00	Wolfenbarger, Jr.	
	A28	6,102,056	08/2000	Kotsopey	
	A29	6,290,718	09/18/01	Grooms et al.	
	A30	6,293,970	09/25/01	Wolfenbarger, Jr.	
	A31	6,440,444	08/27/02	Boyce et al.	
	A32	6,482,584	11/19/02	Mills et al.	
	A33	6,497,726	12/24/02	Carter et al.	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450 Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known		
				Application Number	10/828,653	
Sheet		2	Of	3	Filing Date	April 20, 2004
					First Named Inventor	C. Randal Mills et al
					Group Art Unit	3738
					Examiner Name	Not Yet Assigned
					Attorney Docket Number	15672US01

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	A34	6,613,278	09/02/03	Mills et al.	
	A35	6,652,592	11/25/03	Grooms et al.	
	A36	6,652,818	11/05/03	Mills et al.	
	A37	6,685,626	02/03/04	Wironen	
	A38	6,696,073	02/24/04	Boyce et al.	
	A39	6,699,252	03/02/04	Farr, II, et al.	
	A40	D461,248	08/06/02	Bianchi et al.	
	A41	2001/0031254	10/18/01	Bianchi et al.	
	A42	2002/0106393	08/08/02	Bianchi et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A43	EP 0424159	10/1990			
	A44	JP 03/224570	01/1990			
	A45	WO 94/11035	05/1994			
	A46	WO 97/27882	07/1997			
	A47	WO 98/41245	09/1998			
	A48	WO 99/47080	09/1999			

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	A49	Piet, M.P.J., et al., The use of tri(n-butyl) phosphate detergent mixtures to inactivate hepatitis viruses and human immunodeficiency virus in plasma and plasma's subsequent fractionation, Transfusion vol. 30, No.: 7, 1990, pp. 591-598.
	A50	Hellstern, et al., Vox Sang, 1992:63:178-185, Manufacture and in vitro Characterization of Solvent/Detergent-Treated Human Plasma.
	A51	Horowitz, B. et al., Solvent/Detergent-Treated Plasma: A Virus-Inactivated Substitute for Fresh Frozen Plasma.
	A52	Carr, James, et al. "A Feasibility Study for Removing Tissue Contamination from Porous Implants." Biomedical Instrumentation and Technology. May/Jun. 1995. 220-225.
	A53	Levine, David, et al. "Cost Awareness and Containment for the 1990's: Recycling Orthopaedic Implants." Contemporary Orthopaedics, Oct. 1992. 25(4): 376-381.
	A54	American National Standard. "Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices." Association for the Advancement of Medical Instrumentation, 1991. 1-14.
	A55	Brown, John Stuart. "An Ultrasonic Cleaning Bath in General Practice." Practitioner, Apr. 8, 1988. 232: 377.

EXAMINER	DATE CONSIDERED
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(use as many sheets as necessary))			
Sheet	3	Of	3

OTHER ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	A56	University of Florida Tissue Bank, Inc. "Threaded Cortical Dowel: Processing and Screening Methods." Technical Monograph, 1996. 1-6.
	A57	Grafton Demineralized Bone Matrix (DBM) "First Consider the Source: Musculoskeletal Transplant Foundation." Osteotech, Inc., 1995.
	A58	Wolfenbarger, et al. "A Comprehensive Study of Physical Parameters, Biomechanical Properties, and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery." Spine, 1994. 19(3): 277-283.
	A59	Stanford, C.M. et al. "Bone Cell Expression on Titanium Surfaces is Altered by Sterilization Treatments." J Dent Res, May 1994. 73(5): 1061-1071.
	A60	Evanoff, Jean. "Sterilizing and Preserving Human Bone." AORN Journal, Apr. 1983. 37(5): 972-980.
	A61	Petri, W.H., et al. "Demineralized Bone Sterilization." J Dent Res, 1993. 72 (IADR Abstracts) 417.
	A62	Bloom, D.S., et al. "Effects of Multiple Sterilization in the Monocortical Screw-Bone Interface." J Dent Res, 1996. 75 (IADR Abstracts) 335.
	A63	Liu, Yu et al. "Detergent Treatment on Canine Tracheal Allograft." Transplantation, 1999. 67(9): S649.
	A64	Voggenreiter, G. et al. "Effects of Preservation and Sterilization on the Biomechanical Properties of Cortical Bone Grafts." J. Biomechanics, 1991. 24(6): 458.
	A65	Mschvidobadse, Von M.V. "Allogenic Transplantation of Sterilized Bones and Halfjoints." Zbl. Chirurgie, 1978. 103: 1138-1148.
	A66	American Red Cross, "Aseptically-Processes Bone and Connective Tissue." ARC, North Central Region, 1995.
	A67	Database WPI, Section PQ, Week 199429, Dewett Publications, Ltd., London, GB; Class P32, AN 1994-239698, XP002135434 & SU 1 811 817 A (Traumatology Orthopaedy Res Inst.), Apr. 30, 1993 abstract.
	A68	Maddox, EWA, et al. "Optimizing Human Demineralized Bone Matrix for Clinical Application" Burgess, 529-534.

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